

## **REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein amendment and remarks, which place the application in condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1, 18, 29, 31, and 37 are currently under consideration and claim 37 is amended. Support for the amendment can be found throughout the specification as originally filed, for example, on page 8, lines 17-19. No new matter is added.

### **II. THE REJECTION UNDER 35 U.S.C. § 112 ARE OVERCOME**

Claims 1, 18, 29, and 31 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action at 2. According to the Office Action, "the recitation of antibody or binding fragment thereof which binds to an MHC class II molecule in claim 1 has no written support in the specification and the claims as originally filed." *Id.* at 3. The Office Action also alleges that, in claim 29, the polynucleotide sequence encoding the antibody or antibody fragments is not adequately described. *Id.* This rejection is traversed.

Applicants assert that one of ordinary skill in the art would recognize that the inventors were in possession of the claimed invention at the time the present application was filed. Regarding the rejection concerning the recitation of claim 1, the specification recites that the first sequence may comprise "a polypeptide that is capable of binding to a MHC class II molecule." Specification, p.12, ll.17-19. The specification also indicates the first sequence may "take the form of an antibody to an APC surface molecule." *Id.*, p.13, ll.12-13. Given that a MHC class II molecule is an APC surface molecule, the skilled artisan would recognize that the specification supports an antibody (or binding fragment thereof) that binds to an MHC class II molecule.

Regarding the rejection concerning the recitation of claim 29, Applicants remind that information which is well known in the art need not be described in detail in the specification. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986). With this in mind, Applicants assert that several antibodies or fragments thereof that bind to APC surface molecules were known in the art. For example, U.S. Patent No.

7,030,228 discloses anti-BDCA antibodies that bind to APC surface molecules. Therefore, one of ordinary skill in the art would understand that the specification, combined with knowledge in the art, provides adequate written description for polynucleotide sequences encoding such antibody or antibody fragments.

For at least these reasons, Applicants assert that the instant claims comply with the written description requirement. Accordingly, Applicants request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

### **III. THE REJECTION UNDER 35 U.S.C. § 103(a) ARE OVERCOME**

Claims 1, 18, 29, 31, and 37 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 7,030,228 ("228 patent") in view of U.S. Publication No. 2005/0137130 ("130 publication"). Office Action at 4. According to the Office Action, the '228 patent relates to a fusion protein comprising an anti-BDCA antibody fused to a second polypeptide or an effector molecule such as a cytokine or toxin. *Id.* The Office Action contends that the '228 patent does not teach that the polypeptide to which the antibody is fused is human Delta 1 comprising the SEQ ID NO: 40, and the Office Action turns to the '130 publication as teaching human Delta 1 comprising SEQ ID NO: 40. *Id.* This rejection is traversed.

Initially, Applicants remind that a claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination and the combination yields more than predictable results. *Crocs, Inc. v. U.S. Int'l Trade Comm'n.*, 598 F.3d 1294 (Fed. Cir. 2010). In this case, the Office Action applies human Delta 1 disclosed in the '130 publication as the second polypeptide to which the antibody of the '228 patent is fused. Based on the teachings of the '130 publication, one of ordinary skill in the art would understand human Delta 1 to be used in the '130 publication as an inhibitor of Notch signaling. *See, e.g.*, '130 publication, ¶¶ 0066-67, 0070-71, 0094, 1099-1102. However, this teaches away from the instant claims that recite that the second sequence or the Notch ligand (or a fragment thereof) retains Notch signaling activity. Thus, the '130 publication teaches away from the claimed invention. In addition, the skilled artisan could not have predicted, based on the teachings in the '130 publication, that the second sequence or Notch ligand of the invention would retain Notch signaling activity.

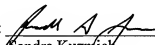
For at least these reasons, the '228 patent and the '130 publication do not render the instant claims unpatentable. Accordingly, Applicants request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

**CONCLUSION**

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

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